December 23, 2003

Donald Lederer
Product Stewardship Manager
Solutia, Inc.
575 Marysville Centre Drive
St. Louis, MO 63141

Dear Mr. Lederer:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Terphenyl, Partially Hydrogenated posted on the ChemRTK HPV Challenge Program Web site on August 28, 2003. I commend Solutia, Inc. for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that Solutia, Inc. advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
Partially Hydrogenated Terphenyls

SUMMARY OF EPA COMMENTS

The sponsor, Solutia, Inc., submitted a test plan and robust summaries to EPA for Partially Hydrogenated Terphenyls (CAS No. 61788-32-7) dated August 15, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on August 28, 2003.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties and Environmental Fate. The submitter needs to change the conclusions on biodegradation and to use the measured physicochemical values for the fugacity model.

2. Health Effects. Adequate data are available for all endpoints for the purposes of the HPV Challenge Program. The submitter needs to address the developmental toxicity endpoint and provide a separate robust summary for it. In addition, the submitter needs to address deficiencies in the robust summaries.

3. Ecological Effects. The data are adequate for acute toxicity in fish, invertebrates, and algae. However, a chronic toxicity study in daphnia is recommended.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA COMMENTS ON THE PARTIALLY HYDROGENATED TERPHENYLS CHALLENGE SUBMISSION

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The submitted data for all endpoints are adequate for the purposes of the HPV Challenge Program.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The submitted data for the photodegradation endpoint are adequate for the purposes of the HPV Challenge Program.

Stability in water. The submitter needs to incorporate a technical discussion explaining why this chemical is stable in water in the robust summary.

Biodegradation. On page 11, the submitter indicates that "while not Readily Biodegradable, significant biodegradation has been established in inherent biodegradation studies (SCAS and River Die Away)." EPA believes that this statement is potentially misleading. The SCAS test, although an OECD inherent biodegradability test, is considered the most powerful of all standard biodegradation tests and provides an optimal environment for biodegradation to occur. The result obtained--35%--is quite low for this type of test. Given this and the nature of the SCAS test, the results do not give any indication about the biodegradability of this chemical under environmental conditions. In the River Die-Away test, the duration of the test (50 days) renders the results obtained (68% degradation) of uncertain value at best, relative to the chemical's biodegradability in the environment, since the characteristics of natural water can be expected to change significantly in this period after the water is brought into the laboratory. The submitter

needs to change the conclusions on the biodegradation and indicate that, while not readily biodegradable, the results of these tests support the conclusion that the test substance is eventually biodegradable.

Fugacity. The submitter used default values as inputs when running its fugacity model. The use of estimated values introduces uncertainties that then become magnified in modeling applications. The submitter needs to use the measured physicochemical values reported in the robust summaries as inputs into the model.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Adequate data are available for all endpoints for the purposes of the HPV Challenge Program. The submitter needs to address the developmental toxicity endpoint and provide a separate robust summary for the endpoint with the developmental effects from the two-generation reproductive toxicity study. In addition, the submitter needs to address deficiencies in the robust summaries.

Reproductive toxicity. Although the highest tested level (1000 ppm) for the submitted two-generation reproductive toxicity assay in rats was a NOAEL for both systemic and reproductive toxicity, EPA believes that the data are acceptable for this endpoint. The reproductive toxicity data (weights and histopathology results for gonads) from the 91-day feeding study, which had a LOAEL of 2000 ppm, provide additional supporting information for the reproductive toxicity endpoint.

Developmental toxicity. The submitter needs to correct the omission of the developmental toxicity endpoint and provide a separate robust summary with the developmental effects from the two-generation reproductive toxicity study.

In Table 1 on page 9, symbol "-", not applicable, should be changed to "Y."

Ecological Effects (fish, invertebrates, and algae).

The data are adequate for acute toxicity in fish, invertebrates, and algae. Since no acute toxicity effects were noted, the toxicity was reported as >0.06 mg/L (the water solubility of the test substance). However, EPA recommends a chronic toxicity study in daphnia since the experimental log K_{ow} (6.13 at 23°C) is greater than 4.2.

Specific Comments on the Robust Summaries

Health Effects

Acute toxicity. A robust summary for an acute oral toxicity study in rats exposed to HB-40 omitted the gavage vehicle (if used).

Genetic toxicity (gene mutations). The omitted information for the robust summary on Therminol® 66 includes the criteria for a positive result, name of the positive controls (not just identified by acronyms), and statistical analysis methods.

Ecological Effects

Invertebrates. Missing information includes the identity and the purity of the test substance. The submitter needs to clearly indicate whether the only tested concentration of 1.34 mg/L was the measured or nominal concentration.

Algae. Missing study details include the lighting conditions during the study, cell concentrations, and the

frequency of measurement of cell concentrations.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.